

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control and Prevention**

[60Day-22-22BG; Docket No. CDC-2021-0131]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comments on a proposed information collection project titled Characteristics of Patients with Environmentally-derived Triazole-resistant *Aspergillus fumigatus*. This case report form collects information on demographics, underlying conditions, treatments, and outcomes of patients with triazole-resistant *A. fumigatus* to inform clinical and public health practice.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0131 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8 Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Characteristics of Patients with Environmentally-derived
Triazole-resistant *Aspergillus fumigatus* - New - National Center

for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The environmental mold *Aspergillus fumigatus* (*A. fumigatus*) is the primary cause of invasive aspergillosis and is associated with ~50% mortality in high-risk patients, including stem cell and organ transplant recipients. The use of triazole antifungals has greatly improved survival. However, triazole-resistant *A. fumigatus* infections are increasingly reported worldwide and are associated with increased mortality and treatment failure. Of particular concern are resistant *A. fumigatus* isolates carrying the TR34/L98H and TR46/Y121F genetic resistance markers, which are associated with environmental triazole fungicide use rather than previous patient exposure to antifungals. Infections with these triazole-resistant strains have become common among patients with *A. fumigatus* infections in Europe, Asia, and South America, and have been characterized epidemiologically. However, U.S. reports of isolates carrying TR34/L98H or TR46/Y121F markers are limited, and detailed epidemiologic data are critical to inform public health response.

Through the Antibiotic Resistance Laboratory Network (ARLN), CDC is already receiving *A. fumigatus* isolates from laboratories across the nation. These isolates undergo testing for triazole resistance (defined using minimum inhibitory concentrations or epidemiologic cutoff values set forth by

Clinical and Laboratory Standards Institute). For patients involving triazole-resistant isolates, we plan to use a standardized case report form (CRF) to collect public health surveillance data regarding demographics (e.g., age, sex, race/ethnicity, country of residence), underlying medical conditions, treatments, and outcomes (e.g., vital status at 30 days for initial positive specimen). The CRF would be filled out voluntarily by state and local health departments and contains an optional supplement at the end involving a brief interview (including data on occupational and environmental exposures) of a patient or their representative. The findings would be used to describe the risk factors, clinical features, and outcomes for patients with triazole-resistance *Aspergillus fumigatus*. U.S. data on triazole-resistant *Aspergillus fumigatus* are lacking, although this problem constitutes a major public health threat.

CDC requests OMB approval for an estimated 8 annual burden hours annually for collection from 15 respondents. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State and Local Health Department	Characteristics of Patients with Environmentally-derived Triazole-resistant	15	15	30/60	8

	<i>Aspergillus fumigatus</i>				
Total					8

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Centers for Disease Control and Prevention.

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